
CANCER FACTS

National Cancer Institute • National Institutes of Health

Paclitaxel (Taxol®) and Related Anticancer Drugs

Paclitaxel (Taxol®) is a compound originally isolated from the bark of the Pacific yew tree (*Taxus brevifolia*). It has been approved by the U.S. Food and Drug Administration (FDA) to treat breast, ovarian, and lung cancers as well as AIDS-related Kaposi's sarcoma.

Paclitaxel has a unique way of preventing the growth of cancer cells: it affects cell structures called microtubules, which play an important role in cell functions. In normal cell growth, microtubules are formed when a cell starts dividing. Once the cell stops dividing, the microtubules are broken down or destroyed. Paclitaxel stops the microtubules from breaking down. With paclitaxel, cancer cells become so clogged with microtubules that they cannot grow and divide.

Early Research

In 1984, NCI began clinical trials (research studies with people) that looked at paclitaxel's safety and how well it worked to treat certain cancers. In 1989, NCI-supported researchers at The Johns Hopkins Oncology Center reported that tumors shrank or disappeared in 30 percent of patients who were being given paclitaxel for the treatment of advanced ovarian cancer. Although the responses to paclitaxel were not permanent (they lasted an average of 5 months, some up to 9 months), it was clear that advanced ovarian cancer patients could benefit from the treatment. In

December 1992, FDA approved the use of paclitaxel for ovarian cancer that was resistant to treatment (refractory).

Other clinical trials using paclitaxel have shown that the drug is effective in the treatment of advanced breast cancer. In April 1994, FDA approved paclitaxel for treating breast cancers that recur within 6 months after adjuvant chemotherapy (chemotherapy that is given after the primary treatment to enhance the effectiveness of the primary treatment). At that time, it was also approved for breast cancer that has spread (metastasized) and has not responded to combination chemotherapy.

In August 1997, paclitaxel was also approved by the FDA as a treatment for the AIDS-related cancer called Kaposi's sarcoma. In April 1998, it was approved for first-line therapy for the treatment of ovarian cancer in combination with cisplatin. Most recently, in June 1998, the FDA approved paclitaxel, in combination with other anticancer drugs, to treat common forms of advanced lung cancer.

Like most cancer drugs, paclitaxel has side effects that can be serious. It is important for patients to talk with their doctor about possible side effects from paclitaxel. For example, it can cause temporary damage to the bone marrow. The bone marrow is the soft, sponge-like tissue in the center of large bones that produces cells that fight infection, carry oxygen, and help prevent bleeding by causing blood clots to form. This damage can cause a person to bruise or bleed easily and be more susceptible to infection. However, the benefits for many patients with advanced cancer outweigh the risks associated with this drug.

Current Clinical Trials

Researchers continue to look for new and better ways to use paclitaxel to treat cancer. For example, they are studying paclitaxel for treatment of early breast, ovarian, and lung cancer. Preliminary findings from ongoing clinical trials suggest that combining paclitaxel with other anticancer drugs may be an effective treatment for patients with lymph node-positive breast cancer. Other studies are looking at paclitaxel as a treatment for lymphomas, and stomach, head and neck, and bladder cancers. In addition, researchers are studying ways to overcome some cancers' resistance to paclitaxel.

Paclitaxel Supplies: Old Problems and New Approaches

Early research using paclitaxel was limited due to difficulties in obtaining the drug. The amount of paclitaxel in yew bark is low, and extracting it is a complicated and expensive process. In addition, bark collection is restricted because the Pacific yew is a limited resource located in forests that are home to the endangered spotted owl.

As demand for paclitaxel grew, NCI, in collaboration with other Government agencies and Bristol-Myers Squibb, worked to increase the availability of paclitaxel. Bark collection and processing expanded to increase the short-term supply of the drug while NCI encouraged research to find other sources of paclitaxel and related compounds.

One option is to synthesize paclitaxel. Currently, a semi-synthetic form of the drug is being studied. To produce the semi-synthetic drug, a substance from the needles of yew trees grown for this purpose is chemically changed to produce paclitaxel.

Another alternative is docetaxel (Taxotere®), a substance that is similar to paclitaxel. Docetaxel, like the semi-synthetic paclitaxel, comes from the needles of the yew tree. Docetaxel

has been approved by the FDA to treat advanced breast and nonsmall cell lung cancers that have not responded to other anticancer drugs. The side effects of docetaxel are similar to those related to paclitaxel. The NCI is sponsoring clinical trials to test the effectiveness of docetaxel alone or in combination with other anticancer drugs for several types of cancer, including cancers of the head and neck, prostate, breast, lung, and uterus.

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Sources of National Cancer Institute Information

Cancer Information Service

Toll-free: 1-800-4-CANCER (1-800-422-6237)

TTY (for deaf and hard of hearing callers): 1-800-332-8615

NCI Online

Internet

Use <http://www.cancer.gov> to reach NCI's Web site.

CancerMail Service

To obtain a contents list, send e-mail to cancermail@icicc.nci.nih.gov with the word "help" in the body of the message.

CancerFax® fax on demand service

Dial 301-402-5874 and listen to recorded instructions.

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